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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,217	09/12/2003	Steven Willem Jan Lamberts	50318/004001	7547
21559	7590	01/11/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			MYERS, CARLA J	
		ART UNIT	PAPER NUMBER	
		1634		

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/661,217	LAMBERTS ET AL.
Examiner	Art Unit	
Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-17 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

***Election/Restrictions***

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 8-12 and 15 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as claims 8-12 are directed to distinct methods and claim 15 is directed to methods which utilize distinct molecules of genes and proteins for therapeutic purposes. A reference against one method would not be a reference against the other methods and a reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, and 8-14, drawn to methods of determining the risk of a metabolic disorder by assaying for a polymorphism, classified in class 435, subclass 6.
- II. Claims 4 and 8-12, drawn to methods of predicting the longevity of an individual by assaying for a polymorphism, classified in class 435, subclass 6.
- III. Claims 5-12, drawn to methods of determining the dose of glucocorticoid for administration to an individual by assaying for a polymorphism, classified in class 435, subclass 6.

- IV. Claim 15, drawn to methods of treatment by administering a nucleic acid, classified in class 514, subclass 44.
- V. Claim 15, drawn to methods of treatment by administering a protein, classified in class 514, subclass 12.
- VI. Claims 16 and 17, drawn to methods of identifying an agent for use in treatment of a metabolic disorder, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are drawn to patentably distinct inventions. Each invention is drawn to a distinct method which involves the use of different reagents, involves performing different method steps and/or have different outcomes or objectives. In particular, inventions I-III requires the use of molecules which detect a polymorphism and requires performing method steps of hybridization, amplification or sequencing to detect a polymorphism. However, the objective and outcome of each of inventions I-III are distinct in that in the method of invention I, the detection of a polymorphism provides information regarding the diagnosis of a metabolic disorder; in the method of invention II, the detection of a polymorphism provides information regarding the longevity of an individual; and in the method of invention III, the detection of a polymorphism provides information regarding the dosage of a glucocorticoid. On the other hand, the method of invention IV requires the use of nucleic acids and the administration of nucleic acid to an individual in order to accomplish the objective of increasing life expectancy. The method of invention V requires the use of proteins and the administration of proteins to an individual in order to accomplish the objective of increasing life expectancy. The

method of invention VI requires the use of a test agent and a glucocorticoid receptor polypeptide and requires monitoring the binding of a test agent to the polypeptide in order to accomplish the objective of identifying an agent for treating a metabolic disease.

3. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-VI require different searches that are not co-extensive. For instance, a keyword / literature search for the methods of detecting an polymorphism as a means for diagnosing a metabolic disorder (invention I) would not be co-extensive with a keyword / literature search for methods of extending an individuals life expectancy by administering a gene (invention IV). Further, a finding that the method of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of invention II-VI were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention II-VI are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers  
January 9, 2006

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER